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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,537	02/23/2004	Wadih Arap	UTSC:872US	2636

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/784,537

Applicant(s)

ARAP ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-63 are pending.

Election/Restriction

Restriction to one of the following inventions groups is required under 35 U.S.C. 121:

- I. Claims 1-21, and 48-52, drawn to an isolated peptide that inhibits aminopeptidase A activity, classified in class 530, subclass 300.
- II. Claims 22-23, drawn to a nucleic acid encoding a peptide; classified in class 536, subclass 23.1.
- III. Claims 24-29, drawn to a method for treating cancer comprising administering an anti-aminopeptidase an antibody to a subject; classified in class 424, subclass 93.1.
- IV. Claims 30-42, drawn to a method for treating cancer comprising administering a peptide that binds to aminopeptidase; classified in class 424, subclass 93.1.
- V. Claims 43-47, drawn to a method for imaging cells expressing aminopeptidase by using a peptide; classified in class 435, subset 69.1;
- VI. Claim 53, drawn to an antibody that binds to a peptide; classified in class 530, subclass 388.1.
- VII. Claims 54-55, drawn to a method for inhibiting viral attachment, classified in class 424, subclass 93.2.
- VIII. Claims 56-63, drawn to a method for promoting angiogenesis in a cell or tissue, classified in class 435, subclass 7.23.

If any group from I, II, IV and V is elected, an additional restriction to one of the follow groups is further required under 35 U.S.C. 121:

- A. An isolated peptide comprising SEQ ID NI: 1;
- B. An isolated peptide comprising SEQ ID NO: 2;
- C. An isolated peptide comprising SEQ ID NO: 3.

If any group of inventions A to C is elected, additional restriction to one of the follow groups of inventions are further required under 35 U.S.C. 121:

- a). The peptide coupled with a drug or therapeutic agent;
- b). The peptide coupled with a radioisotope;

Art Unit: 1648

- c). The peptide coupled with a pro-apoptosis agent;
- d). The peptide coupled with an anti-angiogenic agent;.
- e). The peptide coupled with a hormone;
- f). The peptide coupled with a cytokine;
- g). The peptide coupled with a cytocidal agent;
- h). The peptide coupled with a cytostatic agent,
- i). The peptide coupled with a peptide;
- j). The peptide coupled with a peptide or protein;
- k). The peptide coupled with an antibody or antibody fragment;
- l). The peptide coupled with an antibiotic;
- m). The peptide coupled with a hormone antagonist;
- n). The peptide coupled with a nucleic acid;
- o). The peptide coupled with an antigen;
- p). The peptide attached to a molecule complex;

If group d) is elected, please elect one of anti-angiogenic agent listed in claim 10. This is an additional restriction under 35 U.S.C. 121

- 1). The anti-angiogenic agent is thrombspondin;
- 2). The anti-angiogenic agent is angiostatin 5;
- 3). The anti-angiogenic agent is pigment;
- 4). The anti-angiogenic agent is epithelium-derived factor;
- 5). The anti-angiogenic agent is angiotension;
- 6). The anti-angiogenic agent is laminin peptide;
- 7). The anti-angiogenic agent is fibronectin peptides,
- 8). The anti-angiogenic agent is plasminogen activator inhibitor,
- 9). The anti-angiogenic agent is tissue metalloproteinase inhibitor,
- 10). The anti-angiogenic agent is interferon;
- 11). The anti-angiogenic agent is interleukin 12;
- 12). The anti-angiogenic agent is platelet factor 4;
- 13). The anti-angiogenic agent is IP-10;
- 13). The anti-angiogenic agent is Gro- β ;

Art Unit: 1648

- 14). The anti-angiogenic agent is 2- methoxyoestradiol;
- 15). The anti-angiogenic agent is proliferin-related protein;
- 16). The anti-angiogenic agent is carboxinimidotriazole;
- 17). The anti-angiogenic agent is CM101;
- 18). The anti-angiogenic agent is Marimastat;
- 19). The anti-angiogenic agent is pentosan polysulphate;
- 20). The anti-angiogenic agent is angiopoietin 2 (Regeneron);
- 21). The anti-angiogenic agent is interferon-alpha;
- 22). The anti-angiogenic agent is herbimycin A;
- 23). The anti-angiogenic agent is interferon-alpha;
- 22). The anti-angiogenic agent is PNU145156E;
- 24). The anti-angiogenic agent is 16K prolactin fragment;
- 25). The anti-angiogenic agent is PNU145156E;
- 24). The anti-angiogenic agent is Linomide;
- 26). The anti-angiogenic agent is thalidomide;
- 27). The anti-angiogenic agent is pentoxifylline;
- 28). The anti-angiogenic agent is geneistein;
- 29). The anti-angiogenic agent is ITNP-10;
- 30). The anti-angiogenic agent is endostatin;
- 31). The anti-angiogenic agent is paclitaxel;
- 32). The anti-angiogenic agent is Docetaxel;
- 33). The anti-angiogenic agent is polyamines;
- 34). The anti-angiogenic agent is a proteasome inhibitor;
- 35). The anti-angiogenic agent is a kinase inhibitor;
- 36). The anti-angiogenic agent is a signaling peptide;
- 37). The anti-angiogenic agent is accutin;
- 38). The anti-angiogenic agent is cidofovir;
- 39). The anti-angiogenic agent is vincristine;
- 40). The anti-angiogenic agent is bleomycin;
- 41). The anti-angiogenic agent is AGM-1470;

Art Unit: 1648

42). The anti-angiogenic agent is platelet factor 4;

43). The anti-angiogenic agent is minocycline.

If group c) is elected, please elect one of pro-apoptosis agent listed in claim 11. This is an additional restriction under 35 U.S.C. 121

- i). The pro-apoptosis agent is etoposide;
- ii). The pro-apoptosis agent is ceramide sphingomyelin;
- iii). The pro-apoptosis agent is Bax;
- iv). The pro-apoptosis agent is Bid;
- v). The pro-apoptosis agent is Bik;
- vi). The pro-apoptosis agent is Bad;
- vii). The pro-apoptosis agent is camspase-3;
- viii). The pro-apoptosis agent is caspase-8;
- ix). The pro-apoptosis agent is caspase-g;
- x). The pro-apoptosis agent is fas;
- xi). The pro-apoptosis agent is fas ligand;
- xii). The pro-apoptosis agent is fadd;
- xiii). The pro-apoptosis agent is fap-1;
- xiv). The pro-apoptosis agent is tradd;
- xv). The pro-apoptosis agent is faf;
- xvi). The pro-apoptosis agent is rip;
- xvii). The pro-apoptosis agent is reaper;
- xviii). The pro-apoptosis agent is apoptin;
- xix). The pro-apoptosis agent is interleukin-2;
- xx). The pro-apoptosis agent is converting enzyme;
- xxi). The pro-apoptosis agent is annexin V.

If group f) is elected, please elect one of cytokinie listed in claim 12. This is an additional restriction under 35 U.S.C. 121

- aa). The isolated cytokine is IL-1;
- bb). The isolated cytokine is IL-2;
- cc). The isolated cytokine is IL-5;

Art Unit: 1648

- dd). The isolated cytokine is IL-10;
- ee). The isolated cytokine is IL-11;
- ff). The isolated cytokine is IL-12;
- gg). The isolated cytokine is IL-18;
- hh). The isolated cytokine is interferon- γ ;
- ii). The isolated cytokine is IF- α ,
- jj). The isolated cytokine is IF- β ;
- kk). The isolated cytokine is TNF- α ;
- ll). The isolated cytokine is GM-CSF.

If group p) is elected, please elect one of complex listed in claim 13. This is an additional restriction under 35 U.S.C. 121.

- AA). The complex is a virus;
- BB). The complex is a bacteriophage;
- CC). The complex is a bacterium;
- DD). The complex is a liposome;
- EE). The complex is a microparticle;
- FF). The complex is a magnetic bead;
- GG). The complex is a cell.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups from AA) to GG) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different products, e.g. the group AA comprising a peptide complex with a virus, whereas the group BB is a peptide complex with a bacteriophage. The distinctiveness is also shown by their different searching requirement, i.e. the searching for virus does not need to search bacteriophage, the determination of the patentability of virus cannot be determined by searching bacteriophage.

Art Unit: 1648

Inventions of groups from aa) to ll) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different products, e.g. the group aa comprising coupled with IL-1, whereas the group bb is a peptide coupled with IL-2. The distinctiveness is also shown by their different searching requirement, i.e. the searching for IL-1 does not need to search IL-2, the determination of the patentability of peptide coupled with IL-1 cannot be determined by searching a peptide coupled with IL-2.

Inventions of groups from i) to xxi) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different products, e.g. the group i) comprising a peptide coupled with etoposide, whereas the group x is a peptide coupled with fas. The distinctiveness is also shown by their different searching requirement, i.e. the searching for compound etoposid does not need to search polypeptide of Fas, the determination of the patentability of Fas cannot be determined by searching compound etoposide.

Inventions of groups from 1) to 43) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different products, e.g. the group 1) comprising a peptide coupled with thrombospondin, whereas the group 10 is a peptide coupled with interferon. The distinctiveness is also shown by their different searching requirement, i.e. the searching for interferon does not need to search polypeptide of thrombospondin, the determination of the patentability of thrombospondin cannot be determined by searching interferon.

Inventions of groups from a) to p) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different

Art Unit: 1648

products, e.g. the group m) comprising a peptide coupled with a hormone antagonist, whereas the group o) is a peptide coupled with an antigen. The distinctiveness is also shown by their different searching requirement, i.e. the searching for an hormone antagonist does not need to search polypeptide of an antigen, the determination of the patentability of anitgen cannot be determined by searching hormone antagonist.

Inventions of groups from A) to C) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different products, e.g. the group A) is an peptide of SEQ ID NO: 1, whereas the group B) is a peptide of SEQ ID NO: 2. The distinctiveness is also shown by their different searching requirement, i.e. the searching for SEQ ID NO: 1 does not need to search SEQ ID NO: 2, the determination of the patentability of SEQ ID NO: 1 cannot be determined by searching SEQ ID NO: 2.

Inventions 1-74 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to the treatment with different vaccine. Accordingly, the mode of operation, the function, or the effect exhibited by different vaccine is different.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as direct nucleotide synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for one of the Groups are not required for another one of the Groups, restriction for examination purposes as indicated is proper.

Art Unit: 1648

1. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

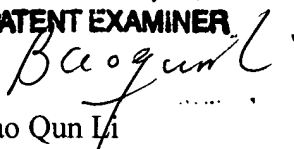
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD
PATENT EXAMINER


Bao Qun Li

1/09/2006